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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GEORGE JACKOWSKI and JOHN MARSHALL

Appeal 2008-5147
Application 09/994,909
Technology Center 1600

Decided:[1] February 2, 2009

Before DONALD E. ADAMS, DEMETRA J. MILLS, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 CFR § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is an appeal under 35 U.S.C. § 134 involving a claim to an isolated biopolymer marker linked to Alzheimer's disease. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

The Claim

Claims 1 is on appeal.[2] Claim 1 reads as follows:

> 1. An isolated biopolymer marker consisting of amino acid residues 2-14 of SEQ ID NO: 1 which evidences a link to Alzheimer's disease.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Robert F. Clark and Alison M. Goate, *Molecular Genetics of Alzheimer's Disease*, 50 ARCHIVES NEUROLOGY 1164-1172 (1993).

R. Motter et al., *Reduction of β-Amyloid Peptide$_{42}$ in the Cerebrospinal Fluid of Patients with Alzheimer's Disease*, 38 ANNALS OF NEUROLOGY 643-647 (1995).

The issue

The Examiner rejected claim 1 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph as lacking utility (Ans. 3, 8).

The Examiner finds that the sole utility claimed for the biopolymer marker in claim 1 is that the marker "evidences a link to Alzheimer's

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[2] Claims 39-46 were withdrawn based upon the restriction requirement in the May 28, 2004 Final Rejection.

disease" (Claim 1; Ans. 6). While the Examiner does not doubt that a marker that is diagnostic of Alzheimer's disease represents a specific utility, the Examiner challenges whether the Specification has demonstrated that the peptide 2-14 of SEQ ID NO: 1 will serve as a diagnostic for Alzheimer's disease under the low utility requirement threshold (Ans. 3-8).

Appellants contend that the "application discloses an invention having specific, substantial, well-established and credible utility by showing an invention that is useful to the public as disclosed in its current form, rather than at some future date after further research, as a peptide marker linked to Alzheimer's disease" (App. Br. 10). Appellants further contend that "Applicants . . . elucidated and identified amino acid residues 2-14 of SEQ ID NO: 1 as a fragment of complement component 3 precursor protein found in healthy, control patients but found to be down-regulated in patients having Alzheimer's disease" (App. Br. 13).

Appellants also contend that "the Examiner has similarly erred by improperly questioning the operability of the invention, in that she states what one of skill in the art would believe without providing evidence to support her conclusion" (App. Br. 21).

In view of these conflicting positions, we frame the utility and enablement issues before us as follows:

Did the Examiner err in finding that the relationship of SEQ ID NO: 1 and Alzheimer's disease failed to satisfy the enablement and utility requirements?

Findings of Fact (FF)

Teachings in the Specification regarding utility and enablement of Biopolymer markers

1. The Specification states that

> The present inventors do not attempt to develop a reference "normal", but rather strive to specify particular markers whose presence, absence or relative strength/concentration in disease vs. normal is diagnostic of at least one specific disease state or whose up-regulation or down-regulation is predictive of at least one specific disease state, whereby the presence of said marker serves as a positive indicator useful in distinguishing disease state.

(Spec. 5:12-20.)

2. The Specification teaches that in analyzing the composition of peptides in human blood, "over 20,000 molecular masses were detected representing an estimated 5,000 different peptides" (Spec. 6:9-10).

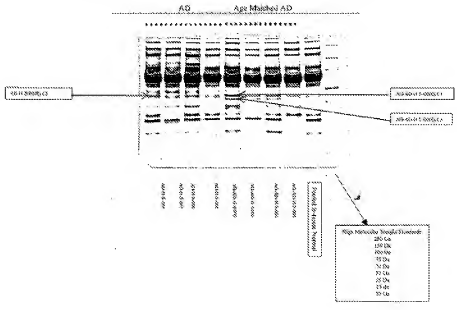
3. The Specification teaches that "[b]iopolymer markers which are present in both disease and normal states are indicative/predictive based upon their relative strengths in disease vs. normal, along with the observation regarding when their signal strengthens/weakens relative to disease manifestation or progression" (Spec. 11:16-20). No specific disease states are specified.

4. The Specification teaches that "[f]igures 1 and 4 are photographs of a gel which is indicative of the presence/absence of the marker in [Alzheimer's] disease vs. control and, in cases where the marker is always present, the relative strength, e.g. the up or down regulation of the

marker relative to categorization of disease state is deduced" (Spec. 46:20-47:2).

5. The Specification discloses Figure 1 which is reproduced below:

DEAE 3(Elution) AD vs. Age Matched AD (Control)
FIGURE 1



"Figure 1 is a photograph of a tricine gel DEAE 3 (Elution) comparing Alzheimer's disease versus Age Matched Control" (Spec. 37:3-4).

Examiner's findings on utility and enablement

6. The Examiner found that the Specification did not disclose "if the fragment 2-14 was present, not present or present at different levels in samples identified as obtained from AD patients" (Ans. 5).

7. The Examiner found that "the instant specification fails to explain the relationship between a peptide 2-14 of SEQ ID NO: 1 and Alzheimer's disease" (Ans. 6).

8. The Examiner found that the Specification fails to teach "experimentation [that] would include determination if a peptide 2-14 of SEQ ID NO: 1 is absent or present or present at particular levels in a specific tissue or body fluid sample of persons suffering from Alzheimer's disease or who are at risk of developing AD *versus* other forms of neurological conditions and normal individuals" (Ans. 7).

Principles of Law

"Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 86 S. Ct. 1033, 1042 (1966). "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Id.*

"Tossing out the mere germ of an idea does not constitute enabling disclosure . . . reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

> We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of *possible use so general as to be meaningless* and then, after his research or that of his competitors has definitely ascertained an actual use for the compound,

> adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

In re Fisher, 421 F.3d 1365, 1375 (Fed. Cir. 2005).

> [T]he PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure…. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility. *See In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981).

In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

Analysis

The sole utility claimed for the biopolymer marker in claim 1 is that the marker "evidences a link to Alzheimer's disease" (Claim 1). While there is no doubt that a marker that is diagnostic of Alzheimer's disease represents a specific utility, the Examiner challenges whether the Specification has demonstrated that the peptide 2-14 of SEQ ID NO: 1 will serve as a diagnostic for Alzheimer's disease under the low utility requirement threshold (Ans. 3-8).

The Specification teaches what biopolymer markers are generically (FF 1-3). The Specification fails to explain how peptide 2-14 of SEQ ID NO: 1 "evidences a link to Alzheimer's disease" as required by claim 1.

The Examiner found that the Specification does not disclose "if the fragment 2-14 was present, not present or present at different levels in samples identified as obtained from AD patients" (Ans. 5; FF 6). Further,

the Examiner found that "the instant specification fails to explain the relationship between a peptide 2-14 of SEQ ID NO: 1 and Alzheimer's disease" (Ans. 6; FF 7). At best, Appellants' Specification discloses that

> Figures 1 and 4 are photographs of a gel which is indicative of the presence/absence of the marker in disease vs. control and, in cases where the marker is always present, the relative strength, e.g., the up or down regulation of the marker relative to categorization of disease state is deduced.

(Spec. 46: 20 - 47: 2.) Essentially, the Specification establishes that the alleged marker can either be present or absent; and if always present then one looks at the whether the alleged marker is up or down regulated. Appellants' Specification fails to establish whether the marker is present or absence in Alzheimer's disease, or whether the marker is up or down regulated in Alzheimer's disease. Stated differently, the Specification identifies a peptide, alleges the peptide is a marker of Alzheimer's disease, and leaves it to those of ordinary skill in the art to figure out how to use the peptide as a marker for Alzheimer's disease.

Appellants have not satisfied the basic quid pro quo embodied by the utility requirement of 35 U.S.C. § 101, which is to teach how to use the invention so that the ordinary practitioner can make use of that knowledge. *See Brenner*, 86 S. Ct. at 1042. ("[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Without specific knowledge of how the peptide of SEQ ID NO: 1 is associated with Alzheimer's disease, the Specification does not provide the ordinary practitioner with a real world, specific, and substantial utility. It was insufficient in *Brenner* and *Fisher* to simply provide potential utilities

without providing the connecting link that allows the ordinary practitioner to use the invention.

In the Jackowski Declaration, the Declarant correctly notes that the comparison between diseased and normal patients would permit identification of potential markers (Jackowski Declaration ¶ 4). However, the Jackowski Declaration does not identify any part of the Specification or drawings in which an actual identification of a marker is made. Further, the Declaration does not address the issues of reproducibility and accuracy in complex and genetically diverse patient populations (FF 8).

The Lander Declaration contends that "decreased expression of the claimed peptide in Alzheimer's disease is also clearly shown" (Lander Declaration ¶ 4). However, neither the photographs of the gels presented in Appellant's Specification nor the photograph of the gel attached to the Lander Declaration, "clearly" shows anything whatsoever. The Examiner found that the photograph of the gels, as originally filed in the Specification, did not clearly show the change in the abundance of the claimed peptide (FF 6) and we find, upon our careful review, that the photograph of the gel cited in the Lander Declaration also does not show any clear change in the abundance of the claimed peptide.

In the instant case, Appellants compound has been identified, but without information in the Specification on how the abundance, presence or other property of the peptide differs between normal and Alzheimer's disease patients, the mere disclosure of a "link" and the polypeptide does not satisfy the utility requirement. The *Fisher* court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public

as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." *Fisher,* 421 F.3d at 1371.

Even though the threshold of utility is low, the Specification must provide more than a compound that requires further use testing in order to determine the actual utility. Appellants contention that the "'link to Alzheimer's disease' . . . was elucidated under real-world conditions" is not found persuasive. (App. Br. 12.) The Specification never describes how the resultant peptides are linked to Alzheimer's disease, which is the central element necessary to satisfy the utility requirement. Just as in *Fisher*, where ESTs were identified, some of which would surely have been useful in analyzing traits of corn or functioning as promoter sequences, the mere identification of the physical molecule was not sufficient. Without the further step of correlating some function of that physical molecule to an actual utility, the compounds failed to satisfy the utility requirement.

We do not find Appellants comparison of research tools to the instant invention an apt comparison (App. Br. 15). Unlike research tools such as gas chromatographs, whose use is instantly evident, the ordinary practitioner would have to do inventive experimentation to determine the use of the claimed marker. Appellants invention is one "whose asserted utility requires further research to identify or reasonably confirm." *Fisher*, 421 F.3d at 1372.

We are not persuaded by Appellants' argument relying upon Gunnersen that "detection of glutamine synthetase in the cerebrospinal fluid

of Alzheimer's disease patients lead to the suggestion of glutamine synthetase as a potential diagnostic marker for Alzheimer's disease" (App. Br. 22). As noted by the Examiner, the current fact pattern differs from Gunnersen because no correlation is shown, since the "specification only presents a photograph of a gel containing bands of [a] mixture of unidentified proteins isolated from different subjects with no clear explanation" as to why any one of these bands would be a diagnostic marker for Alzheimer's disease (Ans. 17).

We also are not persuaded by Appellants reliance upon Emmerling and Cooper, which are cited to show that it is reasonable to link the claimed peptide to Alzheimer's disease (*see* App. Br. 23). The issue is not whether it is reasonable to link the peptide but *whether* there is a link based upon the evidence presented and what the link is. As discussed above, without information in the Specification on how the abundance, presence or other property of the peptide differs between normal and Alzheimer's disease patients, the mere disclosure of a "link" does not satisfy the utility requirement.

Conclusion of Law

The Examiner did not err in finding that the disclosure of SEQ ID NO: 1 in the Specification and the relationship of SEQ ID NO: 1 and Alzheimer's disease failed to satisfy the utility and enablement requirements.

SUMMARY

In summary, we affirm the rejection of claim 1 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

cdc

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